

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

In re:)	MDL No. 1456
)	Civil Action No. 01-12257-PBS
PHARMACEUTICAL INDUSTRY)	Subcategory No. 06-11337
AVERAGE WHOLESALE PRICE)	
LITIGATION)	Hon. Patti B. Saris
_____)	
)	
THIS DOCUMENT RELATES TO:)	JURY TRIAL REQUESTED
)	
<i>United States ex rel. Ven-A-Care of the</i>)	
<i>Florida Keys, Inc. v. Schering Corporation,</i>)	
<i>Schering-Plough Corporation and</i>)	
<i>Warrick Pharmaceuticals Corporation</i>)	
Civil Action No. 00-10698)	

**DEFENDANTS SCHERING-PLOUGH CORPORATION, SCHERING CORPORATION,
AND WARRICK PHARMACEUTICALS CORPORATION’S ANSWER
TO RELATOR VEN-A-CARE OF THE FLORIDA KEYS, INC.’S
AMENDED COMPLAINT FOR VIOLATIONS OF THE
FALSE CLAIMS ACT, 31 U.S.C. § 3729, et seq.**

Defendants Schering-Plough Corporation (“Schering-Plough”), Schering Corporation (“Schering”), and Warrick Pharmaceuticals Corporation (“Warrick”) (collectively “Schering/Warrick”) for their Answer to Relator Ven-A-Care of the Florida Keys, Inc.’s Amended Complaint for Violations of the False Claims Act, 31 U.S.C. § 3729, et seq. (“Complaint”) hereby state as follows:

Unnumbered Introductory Paragraph

Schering/Warrick admit that Ven-A-Care of the Florida Keys Inc. (“Ven-A-Care” or the “Relator”) brings this action under the Federal False Claims Act as a qui tam plaintiff on behalf of the United States and on the Relator’s own behalf. Schering/Warrick deny the remainder of the allegations in the introductory paragraph of the Complaint.

I. NATURE OF ACTION

1. Schering/Warrick admit that Ven-A-Care brings this action on behalf of the United States under the False Claims Act, 31 U.S.C. §§ 3729-33, seeking damages, penalties, and other monetary relief. Schering/Warrick deny the remaining allegations in Paragraph 1 of the Complaint.

2. Schering/Warrick admit that Ven-A-Care purports to base its claims on alleged false or fraudulent claims that Schering/Warrick presented or caused to be presented and on alleged false statements that Schering/Warrick made to get false or fraudulent claims paid. Schering/Warrick deny the remaining allegations in Paragraph 2 of the Complaint.

3. Schering/Warrick deny the allegations in Paragraph 3 of the Complaint.

4. Schering/Warrick deny the allegations in Paragraph 4 of the Complaint.

5. To the extent the allegations set forth in Paragraph 5 of the Complaint purport to state legal conclusions, no response is required. To the extent that a response is required, Schering/Warrick deny the allegations.

6. To the extent the allegations set forth in Paragraph 6 of the Complaint purport to state legal conclusions, no response is required. To the extent that a response is required, Schering/Warrick deny the allegations.

II. JURISDICTION

7. The allegations set forth in Paragraph 7 of the Complaint purport to state legal conclusions to which no response is required. To the extent that a response is required, Schering/Warrick deny the allegations.

8. Schering/Warrick are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 8 of the Complaint and, therefore, deny the allegations.

9. Schering/Warrick admit that they transact business in the District of Massachusetts. To the extent the remaining allegations set forth in Paragraph 9 of the Complaint purport to state legal conclusions, no response is required. To the extent that a response is required, Schering/Warrick deny the remaining allegations.

10. The allegations set forth in Paragraph 10 of the Complaint purport to state legal conclusions to which no response is required. To the extent that a response is required, Schering/Warrick deny the allegations.

III. VENUE

11. The allegations set forth in Paragraph 11 of the Complaint purport to state legal conclusions to which no response is required. To the extent that a response is required, Schering/Warrick deny the allegations.

IV. PARTIES

12. Schering/Warrick are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 12 of the Complaint and, therefore, deny the allegations.

13. Schering/Warrick state that to the extent the allegations in the first sentence of Paragraph 13 of the Complaint purport to represent accurately the substance of various statutes, regulations, or other documents, those sources are the best evidence of their contents. To the

extent these allegations differ from the terms of the statutes, regulations, or other documents, Schering/Warrick deny the allegations. Schering/Warrick admit that Ven-A-Care has brought this action on behalf of itself and the United States.

14. Schering/Warrick are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 14 of the Complaint and, therefore, deny the allegations.

15. Schering/Warrick admit that the United States has declined to join the prosecution of this action, but that the United States remains a party to this action. Schering/Warrick are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 15 of the Complaint and, therefore, deny the allegations.

16. Schering/Warrick admit that Warrick is a Delaware Corporation which had or has a place of business at 12125 Moya Moulevard, Reno, NV, that Schering is a New Jersey Corporation which has a place of business in Kennilworth, New Jersey, and that Schering-Plough is a New Jersey Corporation which has a place of business in Kenilworth, New Jersey. Schering/Warrick admit further that Schering-Plough is the parent of Schering and that Schering is the parent of Warrick. To the extent the allegations set forth in Paragraph 16 of the Complaint purport to state legal conclusions, no response is required. Schering/Warrick deny the remaining allegations set forth in Paragraph 16 of the Complaint.

V. THE LAW

A. The False Claims Act

17. Schering/Warrick state that to the extent the allegations in Paragraph 17 of the Complaint purport to represent accurately the substance of various statutes, regulations, or other

documents, those sources are the best evidence of their contents. To the extent the allegations differ from the terms of the statutes, regulations, or other documents, Schering/Warrick deny the allegations.

18. Schering/Warrick state that to the extent the allegations in Paragraph 18 of the Complaint purport to represent accurately the substance of various statutes, regulations, or other documents, those sources are the best evidence of their contents. To the extent the allegations differ from the terms of the statutes, regulations, or other documents, Schering/Warrick deny the allegations.

B. The Federal Anti-Kickback Statute

19. The allegations set forth in Paragraph 19 of the Complaint purport to state legal conclusions to which no response is required. Schering/Warrick state further that to the extent the allegations in Paragraph 19 of the Complaint purport to represent accurately the substance of various statutes, regulations, or other documents, those sources are the best evidence of their contents. To the extent the allegations differ from the terms of the statutes, regulations, or other documents, Schering/Warrick deny the allegations. Schering/Warrick deny the remaining allegations in Paragraph 19 of the Complaint.

20. The allegations set forth in Paragraph 20 of the Complaint purport to state legal conclusions to which no response is required. Schering/Warrick state further that to the extent the allegations in Paragraph 20 of the Complaint purport to represent accurately the substance of various statutes, regulations, or other documents, those sources are the best evidence of their contents. To the extent the allegations differ from the terms of the statutes, regulations, or other

documents, Schering/Warrick deny the allegations. Schering/Warrick deny the remaining allegations in Paragraph 20 of the Complaint.

VI. THE MEDICAID PROGRAM

A. THE PROGRAM

21. Schering/Warrick are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 21 of the Complaint and, therefore, deny the allegations.

22. Schering/Warrick admit that Medicaid is a joint federal-state program that provides health care benefits for certain groups including the poor and disabled.

B. FUNDING

23. Schering/Warrick state that to the extent the allegations in Paragraph 23 of the Complaint purport to represent accurately the substance of various statutes, regulations, or other documents, those sources are the best evidence of their contents. To the extent the allegations differ from the terms of the statutes, regulations, or other documents, Schering/Warrick deny the allegations.

24. Schering/Warrick are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 24 of the Complaint and, therefore, deny the allegations.

25. The allegations set forth in Paragraph 25 of the Complaint purport to state legal conclusions to which no response is required. To the extent that a response is required, Schering/Warrick deny the allegations. Schering/Warrick state further that to the extent the

allegations in Paragraph 25 of the Complaint purport to represent accurately the substance of various statutes, regulations, or other documents, those sources are the best evidence of their contents. To the extent the allegations differ from the terms of the statutes, regulations, or other documents, Schering/Warrick deny the allegations.

26. The allegations set forth in Paragraph 26 of the Complaint purport to state legal conclusions to which no response is required. Schering/Warrick state further that to the extent the allegations in Paragraph 26 of the Complaint purport to represent accurately the substance of various statutes, regulations, or other documents, those sources are the best evidence of their contents. To the extent the allegations differ from the terms of the statutes, regulations, or other documents, Schering/Warrick deny the allegations. Schering/Warrick are without knowledge or information sufficient to form a belief as to the truth of certain allegations set forth in Paragraph 26 of the Complaint, and, therefore, Schering/Warrick deny the remaining allegations.

27. The allegations set forth in Paragraph 27 of the Complaint purport to state legal conclusions to which no response is required. To the extent that a response is required, Schering/Warrick deny the allegations. Schering/Warrick state further that to the extent the allegations in Paragraph 27 of the Complaint purport to represent accurately the substance of various statutes, regulations, or other documents, those sources are the best evidence of their contents. To the extent the allegations differ from the terms of the statutes, regulations, or other documents, Schering/Warrick deny the allegations.

28. The allegations set forth in Paragraph 28 of the Complaint purport to state legal conclusions to which no response is required. Schering/Warrick state further that to the extent the allegations in Paragraph 28 of the Complaint purport to represent accurately the substance of

various statutes, regulations, or other documents, those sources are the best evidence of their contents. To the extent the allegations differ from the terms of the statutes, regulations, or other documents, Schering/Warrick deny the allegations. Schering/Warrick are without knowledge or information sufficient to form a belief as to the truth of certain allegations set forth in Paragraph 28 of the Complaint, and, therefore, Schering/Warrick deny the remaining allegations.

29. The allegations set forth in Paragraph 29 of the Complaint purport to state legal conclusions to which no response is required. Schering/Warrick state further that to the extent the allegations in Paragraph 29 of the Complaint purport to represent accurately the substance of various statutes, regulations, or other documents, those sources are the best evidence of their contents. To the extent the allegations differ from the terms of the statutes, regulations, or other documents, Schering/Warrick deny the allegations. Schering/Warrick are without knowledge or information sufficient to form a belief as to the truth of certain allegations set forth in Paragraph 29 of the Complaint, and, therefore, Schering/Warrick deny the remaining allegations.

30. Schering/Warrick are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 30 of the Complaint and, therefore, deny the allegations.

31. Schering/Warrick are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 31 of the Complaint and, therefore, deny the allegations. Schering/Warrick state further that to the extent the allegations in Paragraph 31 of the Complaint purport to represent accurately the substance of various statutes, regulations, or other documents, those sources are the best evidence of their contents. To the extent the allegations differ from the terms of the statutes, regulations, or other documents,

Schering/Warrick deny the allegations. Schering/Warrick deny the remaining allegations set forth in Paragraph 31 of the Complaint.

32. Schering/Warrick deny the allegations set forth in Paragraph 32 of the Complaint.

C. DRUG REIMBURSEMENT

33. Schering/Warrick admit that Exhibit A contains a list of Warrick drugs reflecting Warrick's labeler code. Schering/Warrick are without knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations in Paragraph 33 of the Complaint and, therefore, deny the allegations. Schering/Warrick state further that to the extent the allegations in Paragraph 33 of the Complaint purport to represent accurately the substance of various statutes, regulations, or other documents, those sources are the best evidence of their contents. To the extent the allegations differ from the terms of the statutes, regulations, or other documents, Schering/Warrick deny the allegations.

34. Schering/Warrick admit that they do not submit claims for reimbursement to federal health care programs. Schering/Warrick admit further that providers purchased Schering/Warrick' products through wholesalers, GPOs, and specialty pharmacies. Schering/Warrick deny the remaining allegations set forth in Paragraph 34 of the Complaint.

35. Schering/Warrick are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 35 of the Complaint and, therefore, deny the allegations.

36. Schering/Warrick are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 36 of the Complaint and, therefore, deny the allegations.

37. Schering/Warrick allegations set forth in Paragraph 37 of the Complaint

38. Schering/Warrick admit that, from time-to-time, they reported prices to various publishers, but deny the remaining allegations set forth in the first sentence of Paragraph 38 of the Complaint. Schering/Warrick are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 38 of the Complaint and, therefore, deny the allegations.

39. Schering/Warrick are without knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence of Paragraph 39 of the Complaint and, therefore, deny the allegations. Schering/Warrick deny the remaining allegations set forth in the first sentence of Paragraph 39 of the Complaint.

40. Schering/Warrick deny the allegations set forth in Paragraph 40 of the Complaint.

D. REIMBURSEMENT FORMULAS

41. Schering/Warrick are without knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 41 of the Complaint and, therefore, deny the allegations. Schering/Warrick state further that to the extent the allegations in Paragraph 41 of the Complaint purport to represent accurately the substance of various statutes, regulations, or other documents, those sources are the best evidence of their contents. To the extent the allegations differ from the terms of the statutes, regulations, or other

documents, Schering/Warrick deny the allegations. Schering/Warrick deny the remaining allegations in Paragraph 41 of the Complaint.

42. Schering/Warrick are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 42 of the Complaint and, therefore, deny the allegations. Schering/Warrick state further that to the extent the allegations in Paragraph 42 of the Complaint purport to represent accurately the substance of various statutes, regulations, or other documents, those sources are the best evidence of their contents. To the extent the allegations differ from the terms of the statutes, regulations, or other documents, Schering/Warrick deny the allegations. Schering/Warrick deny the remaining allegations in Paragraph 42 of the Complaint.

43. Schering/Warrick are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 43 of the Complaint and, therefore, deny the allegations. Schering/Warrick state further that to the extent the allegations in Paragraph 43 of the Complaint purport to represent accurately the substance of various statutes, regulations, or other documents, those sources are the best evidence of their contents. To the extent the allegations differ from the terms of the statutes, regulations, or other documents, Schering/Warrick deny the allegations. Schering/Warrick deny the remaining allegations in Paragraph 43 of the Complaint.

44. Schering/Warrick deny the allegations set forth in Paragraph 44 of the Complaint.

45. Schering/Warrick are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 45 of the Complaint and, therefore, deny the allegations. Schering/Warrick state further that to the extent the allegations in Paragraph 45 of

the Complaint purport to represent accurately the substance of various statutes, regulations, or other documents, those sources are the best evidence of their contents. To the extent the allegations differ from the terms of the statutes, regulations, or other documents, Schering/Warrick deny the allegations.

46. Schering/Warrick are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 46 of the Complaint and, therefore, deny the allegations. Schering/Warrick state further that to the extent the allegations in Paragraph 46 of the Complaint purport to represent accurately the substance of various statutes, regulations, or other documents, those sources are the best evidence of their contents. To the extent the allegations differ from the terms of the statutes, regulations, or other documents, Schering/Warrick deny the allegations. Schering/Warrick deny the remaining allegations in Paragraph 46 of the Complaint including those contained in the footnote.

47. Schering/Warrick are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 47 of the Complaint and, therefore, deny the allegations. Schering/Warrick state further that to the extent the allegations in Paragraph 47 of the Complaint purport to represent accurately the substance of various statutes, regulations, or other documents, those sources are the best evidence of their contents. To the extent the allegations differ from the terms of the statutes, regulations, or other documents, Schering/Warrick deny the allegations. Schering/Warrick deny the remaining allegations in Paragraph 47 of the Complaint.

48. Schering/Warrick are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 48 of the Complaint and, therefore, deny the

allegations. Schering/Warrick state further that to the extent the allegations in Paragraph 48 of the Complaint purport to represent accurately the substance of various statutes, regulations, or other documents, those sources are the best evidence of their contents. To the extent the allegations differ from the terms of the statutes, regulations, or other documents, Schering/Warrick deny the allegations. Schering/Warrick deny the remaining allegations in Paragraph 48 of the Complaint.

49. Schering/Warrick are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 49 of the Complaint and, therefore, deny the allegations. Schering/Warrick state further that to the extent the allegations in Paragraph 49 of the Complaint purport to represent accurately the substance of various statutes, regulations, or other documents, those sources are the best evidence of their contents. To the extent the allegations differ from the terms of the statutes, regulations, or other documents, Schering/Warrick deny the allegations. Schering/Warrick deny the remaining allegations in Paragraph 49 of the Complaint.

E. DRUG WHOLESALERS' ROLE

50. Schering/Warrick deny the allegations set forth in Paragraph 52 of the Complaint.

51. Schering/Warrick are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 51 of the Complaint and, therefore, deny the allegations.

VII. DEFENDANTS' SCHEME

A. SCHERING, SCHERING-PLOUGH AND WARRICK OPERATED AS ONE ENTITY

52. Schering/Warrick admit that Warrick was formed in 1993. Schering/Warrick deny the remaining allegations set forth in paragraph 52 of the Complaint.

53. Schering/Warrick deny the allegations set forth in paragraph 53 of the Complaint.

54. Schering/Warrick deny the allegations set forth in paragraph 54 of the Complaint.

B. FRAUD SCHEME

55. Schering/Warrick deny the allegations set forth in Paragraph 55 of the Complaint.

56. Schering/Warrick admit that the NDCs identified in Paragraph 56 of the Complaint are Warrick products for which the Relator asserts claims. Schering/Warrick deny the remaining allegations in Paragraph 56 of the Complaint.

57. Schering/Warrick admit that they marketed and sold their products to their customers. Schering/Warrick deny the remaining allegations set forth in Paragraph 57 of the Complaint.

58. Schering/Warrick deny the allegations set forth in Paragraph 58 of the Complaint

59. Schering/Warrick deny the allegations set forth in Paragraph 59 of the Complaint. Schering/Warrick are without knowledge or information sufficient to form a belief as to the veracity of the attachments referenced in Paragraph 59 of the Complaint, and, therefore, deny any allegations based on them.

60. Schering/Warrick are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 60 of the Complaint and, therefore, deny the allegations. Schering/Warrick state further that, to the extent that the allegations set forth in Paragraph 60 of the Complaint state legal conclusions, no response is required. To the extent that a response is required, Schering/Warrick deny the allegations. Schering/Warrick deny the remaining allegations in Paragraph 60 of the Complaint.

61. Schering/Warrick deny the allegations set forth in Paragraph 61 of the Complaint.

62. Schering/Warrick deny the allegations set forth in Paragraph 62 of the Complaint.

63. Schering/Warrick deny the allegations set forth in Paragraph 63 of the Complaint.

64. Schering/Warrick deny the allegations set forth in Paragraph 64 of the Complaint.

65. Schering/Warrick deny the allegations set forth in Paragraph 65 of the Complaint.

66. Schering/Warrick deny the allegations set forth in Paragraph 66 of the Complaint.

67. Schering/Warrick deny the allegations set forth in Paragraph 67 of the Complaint.

68. Schering/Warrick admit that Warrick reported an AWP for albuterol 17gm inhaler and its refill at launch and did not change the AWP thereafter. Schering/Warrick deny the remaining allegations set forth in Paragraph 68 of the Complaint.

69. Schering/Warrick deny the allegations set forth in Paragraph 69 of the Complaint.

70. Schering/Warrick admit that the published AWP for Albuterol Inhalation Aerosol 17 gm, NDC #59930-1560-01 has been \$21.41 from 1996 to the present. Schering/Warrick are

without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 70 of the Complaint and, therefore, deny the allegations.

71. Schering/Warrick deny the allegations set forth in Paragraph 71 of the Complaint.

72. Schering/Warrick admit that the Warrick products identified in the Complaint were multiple-source drugs. Schering/Warrick are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 72 of the Complaint and, therefore, deny the allegations. Schering/Warrick state further that to the extent the allegations in Paragraph 72 of the Complaint purport to represent accurately the substance of various statutes, regulations, or other documents, those sources are the best evidence of their contents. To the extent the allegations differ from the terms of the statutes, regulations, or other documents, Schering/Warrick deny the allegations. Schering/Warrick deny the remaining allegations in Paragraph 72 of the Complaint.

73. Schering/Warrick deny the allegations set forth in Paragraph 73 of the Complaint.

74. Schering/Warrick deny the allegations set forth in Paragraph 74 of the Complaint.

75. Schering/Warrick deny the allegations set forth in Paragraph 75 of the Complaint.

76. Schering/Warrick deny the allegations set forth in Paragraph 76 of the Complaint.

FIRST CAUSE OF ACTION

(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1))

77. Schering/Warrick incorporate by reference their answers to Paragraphs 1 through 76 as if fully set forth herein.

78. Schering/Warrick deny the allegations set forth in Paragraph 78 of the Complaint

79. Schering/Warrick deny the allegations set forth in Paragraph 79 of the Complaint.

80. Schering/Warrick deny the allegations set forth in Paragraph 80 of the Complaint.

SECOND CAUSE OF ACTION

(False Claims Act: Making or Using False
Records or Statements to Cause Claims to be Paid)
(31 U.S.C. § 3729(a)(2))

81. Schering/Warrick incorporate by reference their answers to Paragraphs 1 through 76 as if fully set forth herein.

82. Schering/Warrick deny the allegations set forth in Paragraph 82 of the Complaint.

83. Schering/Warrick deny the allegations set forth in Paragraph 83 of the Complaint.

84. Schering/Warrick deny the allegations set forth in Paragraph 84 of the Complaint.

THIRD CAUSE OF ACTION

(False Claims Act: Presentation of False Claims;
Making or Using False Statements or Records;
31 U.S.C. § 3729(a)(1), (2); 42 USC 1320a-7(b))

85. Schering/Warrick incorporate by reference their answers to Paragraphs 1 through 76 as if fully set forth herein.

86. Schering/Warrick deny the allegations set forth in Paragraph 86 of the Complaint.

87. Schering/Warrick deny the allegations set forth in Paragraph 87 of the Complaint.

88. Schering/Warrick deny the allegations set forth in Paragraph 88 of the Complaint.

89. Schering/Warrick deny the allegations set forth in Paragraph 89 of the Complaint.

PRAYER FOR RELIEF

Schering/Warrick deny that the United States and the Relator are entitled to a judgment or any other relief as requested in their unnumbered and numbered “WHEREFORE” Paragraphs following Paragraph 89 of the Complaint.

Schering/Warrick hereby deny each and every allegation in the Complaint not expressly admitted above.

AFFIRMATIVE DEFENSES

Without assuming the burden of proof of such defenses that they would not otherwise have, Schering/Warrick assert the following defenses:

First Affirmative Defense

Plaintiff fails to state a claim against Schering/Warrick upon which relief may be granted.

Second Affirmative Defense

Plaintiff’s claims are barred, in whole or in part, by the doctrines of res judicata and collateral estoppel, and the prohibition on double recovery for the same injury.

Third Affirmative Defense

Plaintiff’s claims are time-barred by the applicable statute of limitations.

Fourth Affirmative Defense

Plaintiff’s claims are barred, in whole or in part, by the doctrines of laches, estoppel, and waiver.

Fifth Affirmative Defense

Plaintiff's fail to state with particularity facts to support the fraud allegations and/or the fraudulent concealment allegations against Schering/Warrick.

Sixth Affirmative Defense

Plaintiff Ven-A-Care of the Florida Keys, Inc., lacks standing to pursue this action because the allegations in the Complaint are based upon public disclosures of information and it was not the "original source" of that information. Plaintiff further lacks standing or capacity to bring this action.

Seventh Affirmative Defense

Plaintiff's claims for equitable relief are barred, in whole or in part, by the doctrines of *in pari delicto* and/or unclean hands.

Eighth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by the Relator's and the United States' own negligence or gross negligence.

Ninth Affirmative Defense

Plaintiff's claims are barred, in whole or on part, due to their failure to join indispensable parties.

Tenth Affirmative Defense

Plaintiff's claims are barred, in whole or on part, because any injuries sustained by the United States were the result of its own conduct or the intervening or superseding conduct of third parties.

Eleventh Affirmative Defense

Plaintiff's claims for damages are barred, in whole or in part, because: (1) the United States failed to mitigate its damages, and that failure to mitigate damages should proportionately reduce the recovery of such persons and the allocation of any fault, if any exists, attributable to Schering/Warrick; (2) the Relator and United States would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint; (3) by the doctrine of consent and/or ratification.

Twelfth Affirmative Defense

The applicable statutory ceilings on recoverable damages must limit any damages recovered by Plaintiff from Schering/Warrick.

Thirteenth Affirmative Defense

Plaintiff fails to allege facts or a cause of action against Schering/Warrick sufficient to support a claim for attorneys' fees, multiple damages, and/or legal fees.

Fourteenth Affirmative Defense

Plaintiff's claim for punitive damages against Schering/Warrick cannot be sustained because an award of punitive damages that is subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount of punitive damages that may be imposed, would: (1) violate Schering/Warrick's Due Process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and (2) violate Schering/Warrick's right not to be subjected to an excessive award.

Fifteenth Affirmative Defense

The Complaint fails to sufficiently or specifically plead special damages as required by Fed. R. Civ. P. 9(g).

Sixteenth Affirmative Defense

Plaintiff's claims against Schering/Warrick are barred, in whole or in part, by the existence and terms of the written rebate agreement between Schering/Warrick and the Secretary of the Department of Health and Human Services ("HHS"), on behalf of HHS and all States, entitled, "Rebate Agreement Between the Secretary of Health and Human Services and the Manufacturer Identified in Section XI of this Agreement", which was entered into pursuant to 42 U.S.C. § 1396r-8.

Seventeenth Affirmative Defense

Any recovery sought from Schering/Warrick must be reduced by the benefits and rebates that the United States received from Schering/Warrick.

Eighteenth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, to the extent the claims involve drugs reimbursed without reference to AWP or WAC.

Nineteenth Affirmative Defense

Schering/Warrick hereby give notice that they intend to rely upon any other additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserves their right to amend its answer to assert such defense.

Respectfully Submitted,

/s/ John P. Bueker

John T. Montgomery (BBO #352220)

John P. Bueker (BBO #636435)

Ropes & Gray LLP

One International Place

Boston, Massachusetts 02110-2624

(617) 951-7000

Dated: August 17, 2009

CERTIFICATE OF SERVICE

I hereby certify that on August 17, 2009, a true copy of the above Answer was served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

August 17, 2009

/s/ John P. Bueker
John P. Bueker